

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:  
Robert Hofmeister *et al.*

Serial No.: 10/580,660

Filed: May 26, 2006

For: COMPOSITIONS COMPRISING  
POLYPEPTIDES

Group Art Unit: 1643

Examiner: Unknown

Atty. Dkt. No.: DEBE:066US

Confirmation No.: 1727

**CERTIFICATE OF ELECTRONIC SUBMISSION**

DATE OF SUBMISSION: October 30, 2006

**INFORMATION DISCLOSURE STATEMENT**

**MS AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R. § 1.97(g), (h), this Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be construed to be

an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

The present Information Disclosure Statement is being filed prior to the receipt of a first Official Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. § 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is authorized to deduct the appropriate fees from Fulbright & Jaworski Deposit Account No.: 50-1212/DEBE:066US.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,



Steven L. Highlander  
Reg. No. 37,642  
Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P.  
600 Congress Avenue, Suite 2400  
Austin, Texas 78701  
(512) 474-5201

Date: October 30, 2006

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|--|---|--|--------------------------|
| Form PTO-1449 (modified)                         |   | Atty. Docket No.<br><b>DEBE:066US</b>        | Serial No.<br>10/580,660 |
| List of Patents and Publications for Applicant's |   | Applicant<br><b>Robert Hofmeister et al.</b> |                          |
| INFORMATION DISCLOSURE STATEMENT                 |   | Filing Date:<br>May 26, 2006                 | Group:<br>1643           |
| (Use several sheets if necessary)                |   |  |                          |
| U.S. Patent Documents<br><i>See Page 1</i>       | Foreign Patent Documents<br><i>See Page 1</i> | Other Art<br><i>See Page 1-2</i>             |                          |

## U.S. Patent Documents

| Exam. Init. | Ref. Des. | Document Number | Date | Name | Class | Sub Class | Filing Date of App. |
|-------------|-----------|-----------------|------|------|-------|-----------|---------------------|
|             |           |                 |      |      |       |           |                     |

## Foreign Patent Documents

| Exam. Init. | Ref. Des. | Document Number | Date     | Country | Language |
|-------------|-----------|-----------------|----------|---------|----------|
|             | B1        | EP 1348715      | 11/19/03 | Europe  | English  |
|             | B2        | WO 99/54440     | 10/28/99 | WIPO    | English  |

## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

| Exam. Init. | Ref. Des. | Citation   |
|-------------|-----------|--|
|             | C1        | Arndt et al., "Factors Influencing the Dimer to Monomer Transition of an Antibody Single-Chain Fv Fragment," <i>Biochemistry</i> , 37:12918-12926, 1998.   |
|             | C2        | Bruhl, "Depletion of CCR5-expressing cells with bispecific antibodies and chemokine toxins: a new strategy in the treatment of chronic inflammatory diseases and HIV," <i>J Immunol.</i> , 166:2420-2426, 2001.                            |
|             | C3        | Hoffman et al., "Serial Killing of tumor cells by cytotoxic T cells redirected with a CD19-/CD3-bispecific single-chain antibody construct," <i>International Journal of Cancer</i> , 115:98-104, 2005.                                    |
|             | C4        | Jager et al., "Immune monitoring of tumor cell elimination from malignant ascites during immunotherapy with trifunctional bispecific antibodies," <i>Eur. J. Cancer</i> , 37:S60, 2001.  |
|             | C5        | Kretzschmar et al., "High-level expression in insect cells and purification of secreted monomeric single-chain Fv antibodies," <i>J of Immunological Methods</i> , 195:93-101, 1996.   |
|             | C6        | Kufer et al., "Construction and biological activity of a recombinant bispecific single-chain antibody designed for therapy of minimal residual colorectal cancer," <i>Cancer Immunol. Immunother.</i> , 45:193-197, 1997.                  |
|             | C7        | Lee et al., "Reversible Dimer Formation and Stability of the Anti-tumour Single-chain Fv Antibody MFE-23 by Neutron Scattering, Analytical Ultracentrifugation, and NMR and FT-IR Spectroscopy," <i>J. Mol. Biol.</i> , 320:107-127, 2002. |

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EXAMINER:

DATE CONSIDERED:

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

|  |   |   |                                 |
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### Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

| Exam. Init. | Ref. Des. | Citation   |
|-------------|-----------|--|
|             | C8        | Loeffler <i>et al.</i> , "Efficient elimination of chronic lymphocytic leukaemia B cells by autologous T cells with a bispecific anti-CD19/anti-CD3 single-chain antibody construct," <i>Leukemia</i> , 17:900-909, 2003.                            |
|             | C9        | Loffler <i>et al.</i> , "A recombinant bispecific single-chain antibody, CD19 X CD3, induces rapid and high lymphoma-directed cytotoxicity by unstimulated T lymphocytes," <i>Blood</i> , 95:2098-2103, 2000.  |
|             | C10       | Luellau <i>et al.</i> , "Development of a downstream process for the isolation and separation of monoclonal immunoglobulin A monomers, dimers and polymers from cell culture supernatant," <i>J. Chromatography</i> , 796:165-175, 1998.             |
|             | C11       | Mack <i>et al.</i> , "A small bispecific antibody construct expressed as a functional single-chain molecule with high tumor cell cytotoxicity," <i>PNAS</i> 92:7021-7025, 1995.  |
|             | C12       | Mack <i>et al.</i> , "Biologic properties of a bispecific single-chain antibody directed against 17-1A (EpCAM) and CD3: tumor cell-dependent T cell stimulation and cytotoxic activity," <i>J Immunol.</i> , 158:3965-3970, 1997.                    |
|             | C13       | Maletz <i>et al.</i> , "Bispecific Single-Chain Antibodies as Effective Tools for Eliminating Epithelial Cancer Cells From Human Stem Cell Preparations by Redirected Cell Cytotoxicity," <i>International Journal of Cancer</i> , 93:409-416, 2001. |
|             | C14       | Schoberth <i>et al.</i> , "A New Class of Trifunctional Bispecific Antibodies Mediated Efficient Immunological Purging of Peripheral Blood Stem Cells," <i>Eur. J. Cancer</i> , 37:S51, 2001.  |
|             | C15       | Worn <i>et al.</i> , "Stability Engineering of Antibody Single-Chain Fv Fragments," <i>J Mol Biology</i> , 305:989-1010, 2001.   |

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